



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0303; FRL-9391-7]

Ethalfluralin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of ethalfluralin in or on rapeseed subgroup 20A and sunflower subgroup 20B. This regulation additionally removes the established tolerances in or on mustard, seed; rapeseed, seed; safflower, seed; and sunflower, seed, as they will be superseded by the tolerances established by this final rule. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0303, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal

holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7390; email address: nollen.laura@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl. To

access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.”

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0303 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0303, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at

<http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *<http://www.epa.gov/dockets>*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 25, 2012 (77 FR 43562) (FRL-9353-6), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8007) by IR-4, 500 College Rd. East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR 180.416 be amended by establishing tolerances for residues of the herbicide ethalfluralin, *N*-ethyl-*N*-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl)benzenamine, in or on rapeseed subgroup 20A and sunflower subgroup 20B at 0.05 parts per million (ppm). That document referenced a summary of the petition prepared on behalf of IR-4 by Dow AgroSciences, the registrant, which is available in the docket, *<http://www.regulations.gov>*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the tolerance expression for all established commodities to be consistent with current Agency policy. The reason for this change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for ethalfluralin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with ethalfluralin follows.

A. Reliance on Previous Rulemaking Safety Finding and Risk Assessment

In the **Federal Register** of December 5, 2007 (72 FR 68529) (FRL-8342-2), EPA published a final rule (2007 rulemaking) establishing tolerances for residues of the herbicide ethalfluralin, *N*-ethyl-*N*-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl)benzenamine, in or on dry and fresh dill leaves, mustard seed, potato,

and rapeseed, seed at 0.05 ppm, based on EPA's conclusion that aggregate exposure to ethalfluralin is safe for the general population, including infants and children. Since 2007, there have been no additional tolerance actions for ethalfluralin. The toxicity profile of ethalfluralin has not changed since the 2007 rulemaking.

Except as supplemented by the information described in this unit, EPA is relying on the risk assessment underlying the 2007 rulemaking to establish tolerances of ethalfluralin in or on rapeseed subgroup 20A and sunflower subgroup 20B. Further information about EPA's risk assessment and determination of safety supporting the 2007 rulemaking can be found at <http://www.regulations.gov> in the document entitled: "Ethalfluralin: Human Health Risk Assessment for (IR-4) Proposed Uses on Dill and Potato," document ID number EPA-HQ-OPP-2005-0195-0003. The final rule for the 2007 rulemaking can be found in document ID number EPA-HQ-OPP-2005-0195-0002. Currently, there are tolerances established for residues of ethalfluralin in or on the representative commodities of crop subgroups 20A (rapeseed) and 20B (sunflower seed).

These tolerances were based on adequate residue field trial data. The results of these residue data indicate that no ethalfluralin residues were detected in or on rapeseed and sunflower; therefore, tolerances were established at the limit of quantitation (LOQ) of 0.05 ppm for these commodities. Additionally, ethalfluralin tolerances are established at the LOQ of 0.05 ppm for mustard seed (subgroup 20A) and safflower seed (subgroup 20B). The "no detected residues" finding is further supported by review of the Pesticide Database Program (PDP), where no residues of ethalfluralin were found on any crop from 2007 to 2010. Since the proposed use rates for all commodities in crop subgroup 20A and 20B are the same as what is currently permitted for application to rapeseed and sunflower

seed under the existing registrations, the Agency expects similar ethalfluralin residues to be present on other commodities in subgroups 20A and 20B.

Moreover, rapeseed and sunflower seed, in addition to safflower seed, are by far the most consumed commodities in crop subgroups 20A and 20B; other commodities in crop subgroup 20A and 20B have low rates of consumption, as supported by the fact that all members of subgroups 20A and 20B except sesame, safflower, and mustard are not included in the National Health and Nutrition Examination Survey/“What We Eat in America” (NHANES/WWEIA) dietary survey. EPA does not expect that adding sesame exposures to the ethalfluralin risk assessment to change the overall risk since consumption of sesame and exposure to ethalfluralin residues on sesame are expected to be so minor compared to all the representative crops. As a result, EPA does not expect the establishment of tolerances for the rapeseed subgroup 20A and the sunflower subgroup 20B to increase food exposure from what was assessed in the 2007 risk assessment.

Further, residues from drinking water are not expected to change from the 2007 risk assessment because the application rate for subgroup 20A and 20B will be the same as the currently registered application rate for rapeseed and sunflower. As a result, the addition of the new crops in subgroups 20A and 20B would not change the estimated drinking water concentrations used in the 2007 risk assessment. In addition, since the 2007 risk assessment relied on monitoring data for the cancer assessment, EPA has reviewed the most recent water monitoring data to ensure that the conclusions of 2007 risk assessment are still valid. Data from the U.S. Department of Agriculture’s (USDA) PDP and U.S. Geological Survey, National Water-Quality Assessment Program

(USGS/NAWQA) still show that there have been no detectable or very limited detectable residues of ethalfluralin in sampled drinking water and surface/ground water. PDP sampled 3,515 samples of drinking water between 2006 and 2011, and there were no detects at a limit of detection (LOD) between 30 and 400 parts per trillion (ppt). Likewise, there has been a very low detection frequency (0.8%) of ethalfluralin in the USGS/NAWQA monitoring data in the last search. Therefore, the assumptions in the 2007 risk assessment regarding drinking water are still valid.

Since the dietary risk depends on both consumption (which the Agency does not expect to vary significantly from the 2007 risk assessment) and residue levels (which the Agency expects to remain the same as the 2007 risk assessment), the Agency does not expect the risk from ethalfluralin to change from the 2007 risk assessment.

B. Safety Factor for Infants and Children

1. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. In the preamble to the 2007 rulemaking, EPA explained the decision to reduce the FQPA SF to 1X based on reliable data. For this action, EPA is reducing the FQPA SF to 1X for the following reasons:

a. For the 2007 rulemaking, the toxicity database was considered complete. However, changes to 40 CFR part 158 since the 2007 rulemaking imposed new data requirements for immunotoxicity testing and acute and subchronic neurotoxicity testing for pesticide registration. In 2012, EPA determined that the acute and subchronic neurotoxicity studies are not required for ethalfluralin based on a weight-of-evidence approach, considering all of the available hazard and exposure information. However, the immunotoxicity study remains a data requirement at this time.

Although an immunotoxicity study has not been received by the Agency, there is relatively little concern as there are no indications of immunotoxicity in the toxicology database; it does not appear that ethalfluralin directly targets the immune system. Additionally, ethalfluralin does not belong to a class of chemicals (e.g., the organotins, heavy metals, halogenated aromatic hydrocarbons) that would be expected to be immunotoxic. Therefore, the Agency does not believe that conducting an immunotoxicity study will result in a lower point of departure (POD) than that currently used for overall risk assessment, and the 10X FQPA SF (in the form of a database uncertainty factor (UF_{DB})) is not needed to account for the lack of the study.

b. EPA has fully evaluated the toxicity database of ethalfluralin with respect to the potential for special sensitivity of infants and children, and concludes that there is low concern for pre- and postnatal susceptibility for infants and children. The FQPA SF has been reduced to 1X because:

- i. The toxicity database is adequate to characterize potential pre- and postnatal risk for infants and children.
 - ii. No reproductive or developmental effects were observed in rats.
 - iii. Although there were slight developmental effects observed (skeletal malformations) in rabbits (fetuses), they were seen in the presence of maternal toxicity. Additionally, the dose chosen for acute dietary risk assessment is protective of the slight developmental effects observed in the rabbit developmental toxicity studies.
- c. Based on the discussion in Unit III.A., EPA does not expect dietary exposure to ethalfluralin or residues in drinking water to be underestimated.

C. Conclusion

Based upon the findings supporting the 2007 rulemaking and the information discussed in Unit III., EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children, from aggregate exposures to ethalfluralin residues as a result of establishing the tolerances for rapeseed subgroup 20A and sunflower subgroup 20B. Refer to the 2007 rulemaking, available at <http://www.regulations.gov>, for a detailed discussion of the aggregate risk assessments and determination of safety.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies, two gas chromatography with electron capture detection (GC/ECD) methods, are available to enforce the tolerance expression. These methods are available in the Pesticide Analytical Manual Volume II, section 180.416.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for ethalfluralin.

C. Revisions to Petitioned-For Tolerances

The Agency has revised the tolerance expression to clarify:

1. That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of ethalfluralin not specifically mentioned.
2. That compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of the herbicide ethalfluralin, *N*-ethyl-*N*-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl)-benzenamine, in or on rapeseed subgroup 20A at 0.05 ppm and sunflower subgroup 20B at 0.05 ppm. This

regulation additionally removes established tolerances in or on mustard, seed; rapeseed, seed; safflower, seed; and sunflower, seed.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption

provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 21, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.416:

i. Revise the introductory text of paragraph (a).

ii. Remove the commodities, “Mustard, seed;” “Rapeseed, seed;” “Safflower, seed;” and “Sunflower, seed” from the table in paragraph (a).

iii. Add alphabetically the following commodities to the table in paragraph (a).

The amendments read as follows:

§ 180.416 Ethalfluralin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide ethalfluralin, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only the residues of ethalfluralin, *N*-ethyl-*N*-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl)benzenamine.

Commodity	Parts per million
* * *	* *
Rapeseed subgroup 20A	0.05
* * *	* *
Sunflower subgroup 20B	0.05
* * *	* *

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[FR Doc. 2013-15710 Filed 07/02/2013 at 8:45 am; Publication Date: 07/03/2013]